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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,769

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,769	<b>Applicant(s)</b> SHESTIBRATOV ET AL.	
	<b>Examiner</b> Medina A. Ibrahim	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 06/18/08 in reply to the Office action of 12/13/07 has been entered. Claims 1-25 are cancelled. Claims 26-49 are added. Therefore, claims 26-49 are pending.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

### ***Claim Rejections - 35 USC § 112***

Claims 26-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 12/13/07 for cancelled claims 1-25. In the response filed 06/13/08, Applicant has neither amended the claims to overcome the rejection nor argued against the rejection.

Claim 26 is indefinite in the recitation of "formation of acquired resistance to abiotic and biotic stresses in the leaf discs" because it is unclear what causes the acquired resistance. The claim do not recite that the transformation vector contains a gene for acquired resistance. Dependent claims 27-49 are included in the rejection.

Claims 27-29 are indefinite because it is unclear how a single gene can encode more than one protein or different proteins .

Claim 30 is indefinite for depending upon cancelled claims 2, 3, or 4. The claim is also indefinite because it is unclear how a single gene can encode a combination of different proteins. It is unclear how these proteins are combined. For example, claim 27 recites any target protein; claim 28 recites a protein that lowers necrosis; and claim 29 recites a gene that codes for different PR proteins. Clarification is required to more clearly define the metes and bounds of the claim.

Claim 40 is confusing in the recitation of "the acquired resistance to abiotic and biotic stresses is obtained by excluding growth regulators from the medium" because it is unclear how the acquired resistance can be excluded from the medium since the resistance is not a product. The specification does not shed light on this.

### ***Claim Rejections - 35 USC § 112***

Claims 26-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a transgenic garden strawberry and apple plant comprising preparing leaf discs as explants from stock plants, stagewise inoculation and cocultivation of the explants in media with specified concentrations of specified culture components, does not reasonably provide enablement for a method for producing any transgenic plant comprising method steps that only recite explant preparation without including the specifics of the media that is used during the cultivating with the agrobacterium and regeneration steps. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in

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scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 12/13/07 for cancelled claims 1-25. Applicant's arguments filed 06/13/08 have been considered but are not deemed persuasive.

Applicant argues that the claimed method enhances the level of induced resistance formed in an explant during time intervals between the first and second steps of preparing explants and separating the explants. Applicant states during this time interval, one side of the explant "is healed" by proteins and enzymes induced during wounding and make it possible to maintain stability and lowering necrosis of cells and somatic variations. Applicant also states that the formation of acquired resistance to abiotic and biotic stress in the leaf disc is consistent with the concept of the induction process occurring as a response to wound healing.

Applicant's arguments have been fully considered but are not deemed persuasive because Applicant's arguments are not commensurate in scope with the claims. The claims are drawn to producing a transgenic plant of any species by transforming leaf disc explants via *Agrobacterium tumefaciens* stagewise co-cultivation. The claims only recite explant preparation without the necessary steps and media components and concentrations that are required to transform and regenerate the desired transgenic plants as broadly recited in the claimed method. In addition, Applicant has provided no evidence to support the applicability of the claimed method to all various plant species including woody and non-woody plant species. It is well known in the art that each plant species has a unique requirement of culture conditions,

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chemical components and hormones that are required for efficient transformation and regeneration.

As stated in the last Office action, the state-of-the-art teaches that specific conditions, chemical components and concentrations are required to achieve a successful transformation of a plant. Hansen et al (1999, Trends in Plant Science 4(6):226-231) teach that successful transformation of plants requires target tissues that are competent for propagation or regeneration, an efficient DNA delivery method, and the ability to recover fertile transgenic plants at a reasonable frequency. Hansen et al also teach that there are variables such as the use of feeder cells, alternative Agrobacterium strains, infiltration of the bacterial and the duration and temperature of co-cultivation need to be tested to ensure success (page 228, 2nd column, 3rd paragraph). Hansen et al (US 6, 162, 965, Applicant's IDS) teach transformation of plants via agrobacterium and methods of reducing agrobacterium induced necrosis in plants. At column 1, lines 14-47, Hansen et al state "(w)hile Agrobacterium transformation works well for plants which are naturally infected and transformed by Agrobacterium in the wild to form tumors and/or hairy roots, it does not work for others.....Even some dicotyledonous plants such as grapes, soybean or pepper..... have nevertheless proved difficult to transform in the laboratory because the preferred target tissues for transformation and regeneration seem to respond poorly to Agrobacterium exposure."

Therefore, in the absence of specific guidance regarding how to select a plant species other than strawberry and apple that are suitable in the claimed method and the

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specific culture conditions required for the regeneration of the multitude of plant species required by the claimed method, undue trial and error experimentations would be required for one of ordinary skill in the art to identify potential plant species and then make all possible combinations of media comprising all different kinds of chemical components such as salts, hormones, vitamins, carbon sources and additional additives e.g. explants that have been in stagewise contact with *Agrobacterium*, to identify those, if any that form a transgenic tissue that regenerates to a plant with reduced necrosis and somaclonal variation while exhibiting a desired trait. Therefore, given the breadth of the claims encompassing any plant species; the lack of guidance regarding the specifics of culture and selection medium; unpredictability in the art; and the state of the art as discussed above, the claimed invention cannot be practiced throughout the broad scope without undue experimentation. Therefore, the claims are not enabled. See *In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

See *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): where the court held "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention". See also *in re Fischer*, 166 USPQ 19 24 (CCPA 1970) where the court held the scope of the claims must bear a reasonable correlation with the scope of the enablement.

**Remarks**

The claims are deemed free of the prior art of record.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**Contact information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI

/Medina A Ibrahim/  
Primary Examiner, Art Unit 1638

9/15/2008